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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,585	01/13/2006	Robert S. Foote	DC0261US.NP	1514
26259 7590 12/17/2009 LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053				
EXAMINER				
COUNTS, GARY W				
ART UNIT		PAPER NUMBER		
1641				
NOTIFICATION DATE		DELIVERY MODE		
12/17/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary

Application No.

10/553,585

Applicant(s)

FOOTE ET AL.

Examiner

GARY W. COUNTS

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

The amendments filed 05/01/09 and 07/30/09 are acknowledged and have been entered. Currently, claim 4 is pending and under examination.

Withdrawn Rejections

All rejections of claims not reiterated herein, have been withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4, step d, the recitation "the actual pictogram per milliliter of blood" there is insufficient antecedent basis for this limitation. Although, steps a and c determine a level, steps a and c do not provide antecedent support for the recitation "the actual pictogram per milliliter of blood".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by Zoghbi et al (US 2004/0243010).

Zoghbi et al disclose determining the level of BNP in samples obtained from a patient. Zoghbi et al disclose that the patient can be suspected of having a coronary artery disease (e.g. para 0002, 0019, 0054, 0061). Zoghbi et al discloses the sample can be a blood sample (e.g. p. 9). Zoghbi et al disclose determining the level of BNP in a sample from the patient prior to exercise to establish a baseline (control) and also teaches determining the level of BNP in a sample from the same patient post exercise (abstract, pgs 9-10, particularly p. 10, Table 1, and Example 7). Zoghbi et al discloses that the levels of the BNP are determined in pg/ml before and immediately after exercise of the patient and specifically teaches an increase in the levels after exercise (e.g. see Table 1 and Example 7, lines 1-3 of paragraph 0104). Zoghbi et al specifically teaches comparing the level of BNP 13.4 pg/ml before exercise to that of 26.7 pg/ml

immediately after exercise in the patient. Thus, Zoghbi et al shows an increase (change) of 13.3 pg/ml in the post exercise sample compared to the pre-exercise sample ($26.7 - 13.4 = 13.3$) (greater than 10 pg/ml). Zoghbi et al disclose that levels of BNP increased from baseline to post-exercise. Zoghbi et al disclose that the exercise stress test can be performed with myocardial perfusion imaging wherein a dual isotope, rest-stress protocol is used (p. 6, para. 0070). Zoghbi et al also disclose that the lowest detectable measurement of BNP can be as low as 5 pg/ml (e.g. Example 2).

Response to Arguments

6. Applicant's arguments filed 05/01/09 and 07/30/09 have been fully considered but they are not persuasive.

112 2nd Rejections

Applicant argues antecedent basis for the recitation "the actual pictogram per milliliter of blood" is created in steps (a) and (c) of claim 4. This is not found persuasive because although steps (a) and (c) recite measuring a level, the steps do not explicitly provide antecedent support for the actual pictogram per milliliter.

102 Rejection of Zoghbi

Applicant argues that Zoghbi et al disclose use of an entirely different endpoint for assessing risk of ischemia in patients, including the method involving measurement of blood levels of BNP in the same patient both before and after exercise as taught in Example 5, Table 1, page 9. Applicant states that although BNP increased from

baseline to immediately post exercise in individuals with ischemia as well as those without ischemia, the actual pg/ml change in BNP levels post exercise in patients either with or without ischemia had a median value of 15.5 pg/ml in ischemia patients, i.e. patients diagnosed with ischemia, and that the difference between the change in pg/ml of BNP between ischemic patients and those identified as being not ischemic was not statistically significant (p-value reported to be 0.115). This is not found persuasive because as stated in the previous office action this comparison is between non-ischemic patients vs. ischemic patients (i.e. sample from different patients). The currently recited claims are directed to obtaining first and second samples from the same patient and comparing the second level to the first level. As stated above Zoghbi et al discloses that the levels of the BNP are determined in pg/ml before and immediately after exercise of the patient and specifically teaches an increase in the levels after exercise (e.g. see Table 1 and Example 7, lines 1-3 of paragraph 0104). Zoghbi et al specifically teaches comparing the level of BNP 13.4 pg/ml before exercise to that of 26.7 pg/ml immediately after exercise in the patient. Thus, Zoghbi et al shows an increase (change) of 13.3 pg/ml in the post exercise sample compared to the pre-exercise sample ($26.7 - 13.4 = 13.3$) (greater than 10 pg/ml). Zoghbi et al also shows a difference of greater than 10 pg/ml of BNP immediately after exercise as to pre-exercise in Table 1 in the same patient. Thus, Zoghbi et al is teaching comparing an immediate post exercise BNP level to a pre-exercise level and showing a change in the level of greater than 10 pg/ml of BNP in the immediate post exercise level. Thus, Zhoghbi et al reads on the instantly recited claims.

Conclusion

7. No claims are allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/

Examiner, Art Unit 1641

/Melanie Yu/
Primary Examiner, Art Unit 1641